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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/777,514
Filing Date: February 11, 2004
Appellant(s): ZANG ET AL.

Luke Pedersen (Registration No.45,003)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 26, 2010 and reply brief filed August 23, 2010 appealing from the Office action mailed November 4, 2009. The reply brief filed August

23, 2010 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

This examiners answer replaces the answer mailed on June 24, 2010 and only differs from said answer in that this answer additionally includes an objection to the specification that was included in the final rejection.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 40-44, 46-57, 62, 63, and 65-72

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,951,560	SIMON et al.	09-1999
7,608,105 B2	PAVLOV et al.	10-2009
3,726,180	ROSAN, SR	04-1973
2002/0038123 A1	VISOTSKY	03-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Specification

The amendment filed April 28, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: each new recitation of substantially. Although

appellant appears to have support for constant thread height and pitch, appellant does not appear to have support for the term “substantially” constant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44, 46-57, 62-63, and 65-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 40, 44, 46, 48, 55, 67, and 70 each recite, “a *substantially* constant” thread height or pitch. Although appellant seems to have support for a constant thread height or pitch (support provided in original claim by appellant in response), appellant does not have support for the term “*substantially*” which broadens the dimension to a range such that adjacent threads may have slightly different dimensions. It is unclear whether or not “substantially constant” covers the figures 1a, 1b, wherein there seemingly is a large tolerance since a taper is seen in the figures. If indeed “substantially constant” is shown in fig. 1a, 1b, then slight tapers in the prior art (as shown in the appellants figures) may also be considered “substantially constant”. Claims 41-43, 47, 49-54, 56-57, 62-63, 65-66, 68-69, and 71-72 depend upon the above claims and inherit all problems associated therewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 are rejected under 35

U.S.C. 102(b) as being anticipated by Simon et al. (US 5,951,560, cited previously). Simon discloses an implant (see figs.1-5) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (13), second end (12), at least one continuous uninterrupted thread (14) having a flat crest (16), spanning from the first end to the second end and having a substantially constant thread height (see fig.2, is considered *substantially* constant, there is a small taper, but appears to be just as tapered or "*substantially* constant" as appellants show their threads in fig.1a, 1b of the present application), a recessed engagement (22), a tapered exterior surface from one end to the other (see fig.2), and leading and trailing flanks (17, 18; fig.5) with narrowing clearance therebetween. Simon shows a hex, cylindrical recess, countersunk and bore in fig.2.

Claims 40-42, 44, 50, 52-57, 63, 66, 70, and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Pavlov et al. (US 7,608,105 B2). Pavlov discloses an implant (see fig.1) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (26), second end (24), *at least one* continuous uninterrupted

thread (*plurality* of individual threads, each one uninterrupted seen in fig.1) having a flat crest (peak of thread, seen in fig.1, 10), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (34), a tapered exterior surface from one end to the other (see fig.1, 5), and leading and trailing flanks (fig.1,5) with narrowing clearance therebetween. Pavlov discloses a hex, cylinder and bore (col.4, lines 31-35).

Claims 40, 55, and 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosan, Sr. (US 3,726,180). Rosan discloses an implant (see fig.1) comprising a headless body (10) *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (top), second end (bottom-which is considered to include annular groove 15), at least one continuous uninterrupted thread (12) having a flat crest (peak of thread, seen in fig.1), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (bore 13), a tapered exterior surface from a first diameter to a second diameter (length of 12a; bottom portion of 10), and leading and trailing flanks with narrowing clearance therebetween (see fig.1).

Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Visotsky et al. (US 2002/0038123 A1). Visotsky discloses an implant (see fig.1, 2a) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (30), second end (20), *at least one* continuous uninterrupted thread (*plurality* of individual threads 41, each individual thread is about or less than one revolution, extending from one side of 50 to the next side of 50; each one being uninterrupted seen in fig.1) having a flat crest (peak of thread, seen in fig.1, 4b), spanning from

the first end to the second end (the “at least one” which is considered a plurality or the entire collection of threads does span the full length) and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (31), a tapered exterior surface from one end to the other (see fig.1, 2), and leading and trailing flanks (fig.4b) with narrowing clearance therebetween. Visotsky discloses a hex, cylinder and bore (P0007).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visotsky et al. (US 2002/0038123 A1). Visotsky discloses an implant (see fig.1, 2a) comprising a headless body *configured* to fit snugly into a sinus tarsi (is capable of such placement) comprising a first end (30), second end (20), *at least one* continuous uninterrupted thread (*plurality* of individual threads 41, each one being uninterrupted seen in fig.1) having a flat crest (peak of thread, seen in fig.1, 4b), spanning from the first end to the second end and having a substantially constant thread height (shown as constant height in fig.1), a recessed engagement (31), a tapered exterior surface from one end to the other (see fig.1, 2), and leading and trailing flanks (fig.4b) with narrowing clearance therebetween. Visotsky discloses a hex, cylinder and bore (P0007). Visotsky discloses an implant and method of implantation substantially as claimed. Visotsky discloses insertion of the implant into bone where realignment is necessary (abstract, P0001, P0023), however does not specifically disclose placement into the sinus tarsi. It would have

been obvious to one having ordinary skill in the art at the time the invention was made to implant the implant of Visotsky's into the sinus tarsi, since the sinus tarsi is a bony space in the body sometimes in need of realignment (which has been disclosed to be the purpose of Visotsky's implant).

(10) Response to Argument

The appellant has argued that both the 112 1st paragraph rejection and the objection to the specification are improper and has argued that the specification inherently supports "substantially" constant. The appellant has argued they have support for "substantially constant" in the original claims (noting that figs. 1a, 1b show tapered threads and original claims support substantially constant, thus appellants have support for both tapered and constant threads). The examiner disagrees. The appellant's specification with regards to fig. 1a, 1b, does not disclose the threads 54 to be tapered or constant. The specification only discloses that a thread 54 is present (thread being singular) and discloses possible dimensions for the thread (pg.10). The appellant does not have support for tapered AND constant threads. Only one embodiment is shown/disclosed with regards to figs. 1a, 1b. A thread height of approximately .032 inches is disclosed with respect to these figures. Thus since one thread height with one dimension is disclosed with regards to fig. 1a, 1b, appellants only have support for a constant thread. As only one thread height is disclosed with regards to fig. 1a, 1b, we must assume the figures intend to show a constant thread height and that the figures are not to scale (figs seem to show a slight taper, however spec discloses otherwise). Thus, "substantially" constant is believed by the examiner to not be supported (only constant is), and by allowing "substantially" constant into the claims, this broadens appellants original coverage to tapers as shown in appellants not to scale

drawings. It is further noted that "substantially" constant was not present in the original disclosure, but instead added as an amendment on April 28, 2008.

The appellant has argued that Simon (US 5,951,560) does not disclose "a substantially constant thread height". The examiner disagrees. It is the examiners opinion that if figures 1a and 1b of appellants specification may be considered "substantially constant", than Simon's threads seem equally as "substantially constant" in height. That is a very *minimal* taper angle leaves threads that are of "substantially constant" thread height. Appellant has argued their own figures 1a and 1b are not of a constant thread height, but instead a tapered, and that appellant has support for both tapered and constant thread heights for figures 1a-1b-the examiner disagrees with this argument, see above response to 112 1st rejection. " The appellant's specification with regards to fig.1a, 1b, does not disclose/recite the threads 54 to be tapered or constant. The specification only discloses that a thread 54 is present (thread being singular) and discloses possible dimensions for the thread (pg.10). The appellant does not have support for tapered AND constant threads. Only one embodiment is shown/disclosed with regards to figs.1a, 1b. A thread height of approximately .032inches is disclosed with respect to these figures. Thus since one thread height with one dimension is disclosed with regards to fig.1a, 1b, appellants only have support for a constant thread. As only one thread height is disclosed with regards to fig.1a, 1b, we must assume the figures intend to show a constant thread height and that the figures are not to scale (figs seem to show a slight taper, however spec discloses otherwise)." And thus, if figures 1a-1b may be considered "substantially constant" thread height, it is the examiners position that Simon's threads in figure 2 may also be considered to have a "substantially constant" thread height.

The appellant has argued that Pavlov (US 7,608,105 B2) does not disclose a single continuous and uninterrupted thread spanning the entire length of the body. The examiner disagrees. Although Pavlov does show some interruptions (52), these interruptions are not considered to be *within* the thread, but instead *in between two adjacent threads*-that is in figure 1, approximately 8 individual threads are shown, each thread starting as a groove 52 and ending in an adjacent groove (each thread extends almost one revolutions and are spaced from one another via grooves 52, and the threads themselves are not interrupted). Thus the "at least one" in the claim is defined as one or more and in Pavlov's case, pertains to 8 individual threads, each one of the 8 thread is individually uninterrupted and the at least one (8 threads) also span the full length of the body (the collection spans the entire length). It is noted that the claims do not require a single thread to be continuous and uninterrupted and said single thread spanning the full length of the body-the claims instead require "at least one" which may pertain to a grouping of more than one. The "at least one continuous and interrupted threads" (all eight threads are each continuous and uninterrupted) and the at least one thread (the eight threads) span the full length of the body. If appellant were to claim A continuous uninterrupted thread...this would seemingly overcome Parlov. In fact, it is suggested appellant claim this, since "at least one" continuous thread (thus possibly multiple), each from one end to the other of the implant does not seem to be supported by appellants figures. Figures 1a, 1b only show one continuous uninterrupted thread extending from the first end to the second end (not a plurality-at least one).

The appellant has argued that Rosen (US 3,726,180) does not disclose "at least one continuous and uninterrupted thread...traversing a length...from the first end to the second end". The appellant argues that thread 12 does not extend to each end of the body, is instead cut short

by groove 15. The examiner disagrees. Thread 12 at top of implant has a constant thread height; over region 12a, the outside diameter of implant (at thread crest) reduced/tapers-just as the inner diameter (thread root) is reduced, thus the overall thread height (crest-root) stays constant. See fig.1, col.2, lines 4-23, "thread forms of forming threads 12a are uniform and are also similar to the thread forms of the other thread convolutions 12". It is noted that the taper angle (outside surface of crest) is not required by the claim to be constant, only the thread height is required to be constant (crest-root distance). Groove 15 is still considered part of the second end of the body, thus the thread 12 is considered by the examiner to span the length from the first to second end. It is also noted (with respect to claim 55) that the claims require the tapered circumference to taper from the first diameter to the second diameter (not from the first end to the second end). If appellant were to claim the taper to extend from the first end to the second end, this would seemingly overcome Rosan.

The appellant has argued that Visotsky (US 2002/0038123 A1) does not disclose a single continuous and uninterrupted thread spanning the entire length of the body. The examiner disagrees. Although Visotsky does show some interruptions (50), these interruptions are not considered to be *within* the thread, but instead *in between two adjacent threads*-that is in figure 1, approximately 22 individual threads are shown, each thread being less than one revolution and extending from one side of hole 50 to the next side of a hole 50-the individual threads are spaced from one another via holes 50, and the threads themselves are not interrupted). Thus the "at least one" in the claim is defined as one or more and in Visotsky case, pertains to 22 individual threads, each one of the 22 threads is individually uninterrupted and the at least one (22 threads) also span the full length of the body (the collection spans the entire length). It is noted that the

claims do not require a *single* thread to be continuous and uninterrupted and said single thread spanning the full length of the body-the claims instead require "at least one" which may pertain to a grouping of more than one. The "at least one continuous and interrupted threads" (all 22 threads are each continuous and uninterrupted) and the at least one thread (the 22 threads) span the full length of the body. If appellant were to claim A continuous uninterrupted thread...this would seemingly overcome Visotsky. In fact, it is suggested appellant claim this, since "at least one" continuous thread (thus possibly multiple), each from one end to the other of the implant does not seem to be supported by appellants figures. Figures 1a, 1b only show one continuous uninterrupted thread extending from the first end to the second end (not a plurality-at least one).

The appellant has argued (with regards to claim 72) that Simon does not disclose the direction of incline of the leading flank equal and opposite to the trailing flank. The examiner disagrees. Simon's leading and trailing flanks (17 and 18) are shown clearly in figure 5, wherein close-ups of the angles are shown. The flanks (17 and 18) are clearly inclined in different directions (see fig.5), as the directions are opposite, they may be considered equal as best can be understood by the claim language. It is unclear how a "direction" may be equal to a "direction". It seems appellant instead intended to claim the angles are equal, not the direction.

The appellant has argued (with regards to claim 43) that Visotsky does not disclose a taper angle of between 15 and 20 degrees. The examiner disagrees. Visotsky discloses a range of diameters and lengths for the device (P0027). Visotsky discloses the front end diameter to the back end diameter ratio may range from 1:5 (having a taper angle) to about 1:1 (no taper angle). Visotsky also discloses the length may range from 1-60mm. This wide range of diameters and lengths allow a large variety of taper angles including those within the range claimed.

The appellant has also argued (with regards to claim 67) that Visotsky does not disclose a continuous and uninterrupted thread transversing the entire length of the body. See response to Visotsky arguments above relating to the same argument.

The appellant has argued (with regards to claim 69) that Visotsky does not disclose the entirety of the medical device inserted into the sinus tarsi. Visotsky discloses the rear end *may* be cut off (P0008), thus does not necessarily need to be. This was a 103 rejection and the placement fully into the sinus tarsi (positioning is rendered obvious in the rejection).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Cheryl Miller/

Examiner, Art Unit 3738

Conferees:

/Corrine M McDermott/

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